POLICY AND PROCEDURES

Office of Translational Sciences

Critical Path Innovation Meetings

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PURPOSE

The purpose of this MAPP is to delineate the roles and responsibilities of CDER staff and outline the procedures to be followed for a Critical Path Innovation Meeting (CPIM).

BACKGROUND

A CPIM is a nonbinding scientific dialog between FDA and investigators from industry, academia, patient advocacy groups, and/or government to explore novel ideas with the potential to augment drug development and advance regulatory science and policy.[1] A CPIM is a forum for the general discussion of challenges in drug development—as well as innovative strategies to address them—and is not specific to any particular medical product. The CPIM is not intended to replace discussions with review divisions on drug-specific development efforts.

SCOPE

The scope of the CPIM includes but is not limited to:

- Biomarkers in the early phase of development that are not yet ready for the Biomarker Qualification Program[2]
- Clinical Outcome Assessments in the early phase of development that are not yet ready for the Clinical Outcome Assessment Qualification Program[2]

- Natural history study designs and implementation
- Emerging technologies, or new uses of existing technologies
- Innovative conceptual approaches to clinical trial design and analysis
- Patient-, Clinician-, and Observer-Reported Outcomes Assessments

A CPIM is not a:

- Substitute for formal pre-IND, IND, NDA, BLA, or other regulatory meetings
- Venue for organizations to market commercial products to or seek endorsement from the FDA
- Forum for organizations to obtain FDA's detailed review and analysis of data

Potential outcomes of CPIMs include the initiation of actions leading to:

- Regulatory submissions of clinical trials with new designs and methods
- Proposals for the use of emerging technologies
- Proposals for biomarker qualification or the use of biomarkers in regulatory submissions
- Natural history studies
- Public workshops and future collaborations between FDA and external parties
- Development of new guidance
- Formation of new consortia and public-private partnerships to advance regulatory science efforts

POLICY

- The CPIM program is administered by the Office of Translational Sciences Immediate Office, Strategic Partnerships and Technology Transfer (SPT2) Program.
- Evaluation of materials for and participation in a CPIM by FDA subject matter experts is voluntary and dependent on resources.
- A CPIM is a general discussion that does not involve the detailed evaluation of data.
- A CPIM does not include any discussion of individual drug development programs.
- To the best of their knowledge, CDER and other FDA participants' perspectives during the meeting will be consistent with CDER and FDA policy. Their individual perspectives should not be treated as necessarily describing established policy.
- CPIM discussions and meeting summaries are nonbinding.

ROLES AND RESPONSIBILITIES

CPIM Project Manager

- Notifies CPIM Scientific Lead of CPIM requests
- Reviews CPIM requests and provides input to the Scientific Lead
- Serves as the point of contact with requester and participating FDA centers, offices, and divisions for administrative issues and the transfer of documents
- Works with requester and FDA subject matter experts to establish the date for the CPIM
- Manages CPIM database for knowledge management purposes
- Manages all logistics for the related activities and meetings
- Communicates with the CPIM requester as needed to refine and clarify the nature of a CPIM request
- Directs requester to appropriate FDA center or division if the requester's topics are not appropriate for a CPIM
- Manages monthly updates of CPIM data to the SPT2Dashboard

CPIM Scientific Lead

- Appointed by OTS-IO to provide scientific leadership to the CPIM program
- Evaluates whether a CPIM is an appropriate venue for the issue or topics raised by the requester
- Provides suggestions for the requester to appropriate FDA center or division if the requester's topics are not appropriate for a CPIM
- Chairs the CPIM pre-meeting and CPIM
- Writes the CPIM summary

FDA Centers, Offices, and Divisions

- Identify appropriate staff to participate in specific CPIMs
- Participate in pre-CPIM meeting and CPIM as resources permit
- Edit and comment on draft meeting summary
- There is no expectation that FDA staff will evaluate materials other than the meeting materials or provide written responses.

Requester

- Submits CPIM request form
- Submits CPIM preparation package 2 weeks in advance of the CPIM. This package should include:
    - Agenda
    - Proposed Attendees
    - Objectives
    - Specific questions for the FDA to consider

PROCEDURES

Submission and evaluation of request for CPIM

- The CPIM request form is available on the FDA intranet site at http://inside.fda.gov:9003/downloads/CDER/OfficeofTranslationalSciences/UCM639927.pdf and on the FDA internet site at http://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm395888.htm. This form is directed automatically to the email account CPIMInquiries@fda.hhs.gov.
- The Project Manager will confirm receipt of all CPIM requests.
- Requests referred from other offices or divisions should be directed to the CPIM Project Manager.
- Each request received will be forwarded to the CPIM Scientific Lead.
- The CPIM Scientific Lead will determine if the request is within the scope of the CPIM.
- In some cases, the CPIM Scientific Lead may discuss with the requester modifications to the request form and a resubmission of the form.

Granting or denying a CPIM

- The Project Manager will notify the requester if the CPIM request has been granted.
- If a request for a CPIM is not appropriate, the CPIM Scientific Lead will discuss this with the requester and suggest potential other avenues to address the requester's needs. The Project Manager will connect the requester to the appropriate centers/offices/divisions.

Arranging a CPIM

- The Project Manager will request an information package from the requester of the CPIM no later than 2 weeks prior to the CPIM. Once the information package is received, the Project Manager will distribute the materials received to all proposed participants by loading all materials into the CPIM SharePoint site.

CPIM Activities

- An internal pre-CPIM meeting among the planned FDA participants is scheduled after the meeting package has been received and will be held within 30 days of the scheduled CPIM. The intent of the pre-meeting is to review the meeting materials and discuss FDA participants' perspectives on the meeting topic and requester's questions.
- The Scientific Lead or designee will draft a meeting summary that will be distributed to the FDA participants for comments and edits.
- The final summary will be sent to the requester.

Records Management

File Code	Records Description and Authorized Disposition	NARA Approved Citation
FDA-8510	**Substantial Material.** Background materials relating to significant records, briefings for the Commissioner, external briefings, speeches, and other types of materials with long-term value. **Disposition: TEMPORARY. Media neutral.** Cut off at end of calendar year in which associated project or case is completed. Maintain a minimum of 3 years then destroy 6 years after cutoff or when no longer needed for reference, whichever is sooner.	**N1-088-06-3**
FDA-8510	OTS will maintain an archive of all CPIM records in accordance with the National Archives and Records Administration (NARA) guidance. Records include: CPIM Request forms, summaries, SOPs, Guidance, MaPP, and meeting materials will be stored in the Enterprise Content Management System, Records Management (RM).	**N1-088-06-3**

REFERENCES

1. *Guidance for Industry and FDA Staff (2014) Critical Path Innovation Meetings*. Available at: http://inside.fda.gov:9003/downloads/CDER/OfficeofTranslationalSciences/UCM441995.pdf.
2. *Guidance for Industry and FDA Staff (2014). Qualification Process for Drug Development Tools*. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-process-drug-development-tools-guidance-industry-and-fda-staff.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Revised Date 3/30/2021	1.0	Chekesha S. Clingman - Updated records management information